

### REMARKS

Claims 18, 21, and 23-27 are pending in the present application.

The rejection of Claims 18-19, 21, and 23-27 under 35 U.S.C. §112, first paragraph (written description/new matter), is obviated by amendment.

As requested by the Examiner, Applicants have amended Claim 18 to clearly define the human framework region. Specifically, Applicants have amended Claim 18 to define the human framework region as being a framework region that is substantially identical (at least 85%) to the framework region of a naturally occurring human antibody (see page 6, line 5-18). More specifically, Claim 18 has been amended to define the framework region in the heavy chain as being at least 85% homologous to SEQ ID NO: 5 and the framework region in the light chain as being at least 85% homologous to SEQ ID NO: 7.

Applicants have also amended Claim 18(a) to place the amino acid sequences set forth therein in full compliance with the sequence rules (see 37 C.F.R. 1.821(d)). Support for these sequence assignments is provided by the substitute Sequence Listing filed on July 1, 2002, the original Sequence Listing filed on May 16, 2001, Figure 2a, and Figure 2b.

Applicants note that each of the amendments to Claim 18, as well as the full scope of this claim, are supported by the present application as originally filed. Accordingly, pending Claims 18, 21, and 23-27 do not contain new matter and are in full compliance with the written description requirement of 35 U.S.C. §112, first paragraph.

In view of the amendments and comments herein, Applicants request withdrawal of this ground of rejection.

The rejection of Claims 18-19, 21, and 23-27 under 35 U.S.C. §112, first paragraph (enablement), is obviated by amendment.

The Examiner's rejection appears to be rooted in the lack of an explicit full-length sequence for the light and heavy chains of the claimed immunoglobulin. Accordingly, Claim 18 has been amended to define the framework region in the heavy chain as being at least 85% homologous to SEQ ID NO: 5 and the framework region in the light chain is at least 85% homologous to SEQ ID NO: 7 (see also page 6). Based on this framework, Claim 18 (a) specifically defines the complementarity determining regions in the light chain. From these clearly delineated sequence regions, the skilled artisan would be capable of readily making or using the invention from the disclosure provided by the present application.

MPEP § 2164.01 states:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Applicants submit that determining what sequences fall within or without the scope of the present Claims would be readily apparent to the skilled artisan. Accordingly, based on the foregoing, Applicants submit that the present claims are fully enabled by the specification and the common knowledge available in the art.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 18-19, 21, and 23-27 under 35 U.S.C. §112, first paragraph (enablement), is obviated by amendment.

Applicants have cancelled Claim 19, which the Examiner found objectionable due to the recitation of the term "I3R." It is the Office's position that the I3R antibody needs to be deposited in accordance with the Budapest Treaty as being required to practice the claimed

invention. However, Applicants have canceled Claim 19 and, as such, this phrase does not appear in the claims.

Moreover, at page 6, lines 5-18, the artisan would appreciate that the human framework region is a framework region that is substantially identical (at least 85%) to the framework region of a naturally occurring human antibody. As stated above, Claim 18 has been amended to define the framework region in the heavy chain as being at least 85% homologous to SEQ ID NO: 5 and the framework region in the light chain is at least 85% homologous to SEQ ID NO: 7 (see also page 6). Therefore, the human antibody serving as the framework source is not specifically limited to I3R. The specification further directs that skilled artisan to references such as Queen et al and Co et al, which are incorporated therein, which provide additional information to assist the artisan in obtaining adequate framework region sequences for human antibodies.

Applicants request withdrawal of this ground of rejection.

The rejection of Claims 18-19, 21, and 23-27 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

- a) Appropriate sequence identifiers have now been added to the claims;
- b) Claim 19 has been cancelled and, thus, recitation of I3R has been deleted; and
- c) On page 6 of the present response, support for every amendment made herein has been duly noted.

Consistent with the Examiner's indication, the specification has been reviewed for trademarks. Based on this review, further amendment is believed to be unnecessary.

The objection to the specification, the title, and the Abstract are obviated by amendment. Withdrawal of these objections is requested.

Applicants note the Examiner's indication that "neither the references nor the International Search Report were found upon a review of the documents in this scanned application." Applicants request that the Examiner provide acknowledgment that the references cited on the International Search Report (copy enclosed herewith), which were also cited on the Information Disclosure Statement filed on August 21, 2002, have been considered.


Applicants respectfully request that the Examiner acknowledge consideration of same by providing Applicants with an initialed copy of the Form PTO-1449 enclosed herewith listing this reference. Accordingly, Applicants submit herewith a copy of the Information Disclosure Statement as filed on August 21, 2002, as filed, along with a copy of the references for which consideration is requested and a copy of the date-stamped filing receipt evidencing the timely filing thereof.

Finally, Applicants request that the Office hold the obviousness double-patenting rejection of Claims 18-19, 21, and 23-27 over U.S. 6,613,328 and the provisional obviousness double-patenting rejection of Claims 18-19, 21, and 23-27 over U.S. 10/289,181 in abeyance until such a time as allowable subject matter has been identified in the present application.

Applicants submit that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



Stephen G. Baxter, Ph.D.  
Attorney of Record  
Registration No. 32,884

Vincent K. Shier, Ph.D.  
Registration No. 50,552

Customer Number

**22850**

(703) 413-3000  
Fax #: (703) 413-2220  
SGB:VKS